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ENVIRONMENTAL PROTECTION

State Water Resources Control Board

Division of Drinking Water

November 3, 2016

Laboratory Community,

Thank you for joining us Monday for our third and final Expert Review Panel Quarterly Update. We appreciate your time and feedback. Attached we have provided a summary of the questions asked by the Panel and community members by category, and ELAP's responses.

A recording of the meeting is available at www.sccwrp.org/elap if you were unable to attend and would like to watch at your convenience.

Thank you,

A handwritten signature in blue ink, reading "Christine Sotelo".

Christine Sotelo
Chief of ELAP

FELICIA MARCUS, CHAIR | THOMAS HOWARD, EXECUTIVE DIRECTOR

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The TNI Standard and TNI Resources

Question	Is the 2016 TNI Standard fully approved?
Answer	Nearly. Any changes made at this point can only be non-substantive.

Question	When is the TNI Standard available to laboratories at the discounted member rate?
Answer	Immediately. Visit www.nelac-institute.org .

Question	How long will the discount be available on the standard document?
Answer	Always. TNI has committed to providing all California laboratories the Standard document at member rates.

Question	Will TNI Checklists be made available for free?
Answer	TNI Checklists are always available for free on the TNI website to any person who owns a copy of the standard. The 2016 checklists are expected to be available soon.

State Water Board Workshop and ELAP's Regulations Development

Question	What happened at the State Water Board Workshop? What was the outcome?
Answer	The October 6 th Public Workshop was a chance for ELAP staff to present their preliminary recommendation to the Board Members and the community. The Board Members were able to hear feedback from stakeholders on the decision. They did not make any formal decision at the workshop. However, through comment and question at this event and subsequent individual meetings with program management, they did endorse the decision ELAP has made to use the TNI Standard and modify the requirements by working with the stakeholder community.

Question	How will stakeholder comments be used in the regulations development process?
Answer	Stakeholder comments will be used in several ways during development of draft regulation text: <ol style="list-style-type: none">1. A summary of stakeholder comments will be presented to ELTAC on November 2nd before their deliberations on recommendations for modifications of the standard.2. All comments will be used during internal deliberations when staff is developing the draft text.3. Stakeholder comments received before and during the Draft Regulations

	<p>Workshops in 2017 will be used by staff during internal deliberations when revising the draft text.</p> <p>4. ELAP will post a formal response to comments on the program’s webpage during the rulemaking process.</p>
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Question	How will the TNI Standard be “modified”?
Answer	ELAP will incorporate the TNI Standard document by reference into the draft regulation text. This means that only the title and edition will appear, along with language similar to “Laboratories must comply with the requirements in the document”. ELAP will then “modify” the requirements in the TNI Standard by listing the section to be “modified” and the “modification” in the draft regulation text, which will supersede the TNI section.

Question	When does submittal of draft regulations happen?
Answer	We anticipate releasing the draft text to the stakeholder community in early 2017. Submittal to the Office of Administrative Law happens only after ELAP fulfills the requirements in the Administrative Procedures Act. See the California Rulemaking Roadmap on ELAP’s website for an overview. The dates for release and submittal of the regulations are flexible.

Laboratory Implementation of the TNI Standard

Question	What will the implementation time period be after adoption of regulations for laboratories to comply with the new standard?
Answer	We anticipate recommending a three year implementation period and a future compliance date to be written into the regulation text; however, this is subject to State Water Resources Control Board approval.

Question	How will ELAP minimize the costs to laboratories associated with adoption of a new standard?
Answer	ELAP is committed to minimizing costs to laboratories. We have negotiated preferred rates on the standard document and free templates for laboratories to use to minimize up-front costs. However, ELAP sees the majority of cost associated with implementation in the staff time required to bring a laboratory into compliance with new requirements. To address those costs, we will provide a robust assistance program with training tools, workshops, webinars, dedicated staff, on-site assistance through the assessor training contract, and an extended compliance date to allow more time to implement the standard.

Question	Will ELAP build its own PT program?
Answer	No. ELAP will continue to require one passing proficiency test per year for certification. At this time we are requiring it be from one of the TNI-approved providers, but we are open to discussing adding additional providers to our list during the regulations development process.

Assessments and the Assessor Training Contract

Question	Will California use a third-party contractor to assess California laboratories?
Answer	Only during ELAP’s Assessor Training Contract as a teaching tool for ELAP’s assessors. Once the contract concludes, ELAP staff will perform all California ELAP assessments. Our intention is that these third-party assessments also serve as a training tool for the laboratories, who may ask questions about the TNI requirements and even have a “mock” assessment of the quality management system elements they have implemented. No laboratory will be held to the TNI requirements until the date specified in regulations, which will be after the close of the training contract.

Question	Does the contract provide tools for ELAP to continue implementing the training program after it is over?
Answer	Yes. The Contractor will identify and train two ELAP staff members on implementing the training program so that future staff goes through the same process. We call this the “Train-the-Trainer” model. The assessor training program will also be written into ELAP Standard Operating Procedures and become a part of the program’s quality management system.

Question	Can ELAP share the content of the contract at this time?
Answer	No. The content cannot be shared with the public before release for bids. This is to eliminate any chance of one or more bidders getting a “head-start” on qualifying or developing proposals. ELAP anticipates the contract being released publicly for bids during November.

Reciprocity

Question	Does California accept certification from other Accrediting Bodies as a basis for certification?
Answer	Yes. Laboratories must submit a certificate and scope, official report from the accrediting body’s on-site assessment, and the laboratory’s corrective action response when applying for reciprocity certification. If approved, the laboratory will not need an assessment from California ELAP.

Question	Why do I need to pay a full fee to California if I am certified through reciprocity?
Answer	ELAP fees support a full program, including many activities outside of laboratory assessments. We will discuss revising the fee structure at the January 4 th ELTAC meeting.

The State of ELAP

Question	Where is ELAP in the process of writing the SOPs for the program's Quality Management System?
Answer	ELAP has created and is implementing 29 new SOPs for its internal management system. We had originally identified that there were approximately 50 SOPs necessary. During this process, we have been finding additional processes that need to be documented as part of the program quality management system, and some that were actually part of other SOPs. We anticipate identifying other changes to our original plan as we move forward with implementing ELAP's quality management system.

Question	What will be the cost to ELAP for adoption of the TNI Standard?
Answer	The economic and fiscal impact of the proposed regulations will be released with the draft regulation text.

Question	Is it fair that the laboratories be held to the TNI Standard and ELAP not be held to the same?
Answer	ELAP is voluntarily implementing the TNI Standard, Volume 2, General Requirement for Accreditation Bodies Accrediting Environmental Laboratories (with ISO 17011). While we are not an official accrediting body, we are holding ourselves to the same standard as the states that are.

Question	Is California going to become an official TNI Accrediting Body?
Answer	California will eventually consider a return to national program, although this is not a goal for the next several years. There are much higher-priority issues that ELAP must resolve before a return will be considered, including the need to develop a program that is internally robust and acceptable to the State Agency Partners, as well as the laboratories it accredits.